

REMARKS/ARGUMENTS

This Amendment is filed in response to the Office Action mailed June 3, 2009. The claims remain unchanged. Claims 7-27 remain withdrawn. Following entry of this Response, claims 1-6 shall be pending for examination.

In the Office Action, claims 1-6 have been rejected based on prior art grounds. The applicant hereby requests reconsideration of the currently pending claims in view of the remarks set forth below.

I. **REJECTIONS UNDER 35 USC 102(e) AS BEING ANTICIPATED BY U.S. PATENT NO. 6,752,813 GOLDFARB**

Previously, claims 1-6 were finally rejected under 35 U.S.C. 102(b) as being anticipated by *Goldfarb*. The Examiner asserted that "*Goldfarb* discloses a method of reinforcing a native valve (LV) comprising implanting a reinforcing support to at least one valve leaflet, said support allowing a free edge of the at least one valve leaflet to form a seal with free edges of adjacent leaflets during diastole..."

The Applicants pointed out, in a telephonic interview and again in a response filed on March 26, 2009, an important distinction between *Goldfarb* and the claimed invention: *Goldfarb* attempts to restore valvular function by permanently connecting two free edges together. The present invention, on the other hand, attempts to restore valvular function by supporting a leaflet such that the free edges of the leaflet can form a seal with free edges of adjacent leaflets during a diastole. This is an important distinction because *Goldfarb* restores the ability of the valve to stop retrograde flow, however, because the joined edges remain joined during antegrade flow, the valve loses its native functionality.

This distinction is found in Claim 1, which claims, "...said support allowing any free edges of the at least one valve leaflet to form a seal with free edges of adjacent leaflets during diastole." *Goldfarb*, by joining two leaflets together, is effectively taking

two leaflets and combining them into one large leaflet. Thus, the free edges affected by the *Goldfarb* device are no longer free. In other words, after the *Goldfarb* method is performed on a valve, the support applied is not allowing free edges to form a seal, rather, it is simply reducing the number of non-functioning free edges.

In order to further distinguish the claimed method from *Goldfarb*, the Applicants previously amended Claim 1, changing "a free edge" to "any free edges." Each leaflet has a free edge in its native state, which coapts with the free edge of both adjacent valves to form a "Y" shape when all of the free edges are coapting. Hence, though the free edge of a leaflet is continuous, each free edge can be considered two free edges in the coapted state. The present device and method restores functionality to both halves. Thus, the support allows any free edges of the valve leaflet to form a seal with free edges of adjacent leaflets during diastole. *Goldfarb*, on the other hand, eliminates one of the free edges (or one half of the edge during systole) of a leaflet, leaving only one remaining free edge to form a seal with the adjacent leaflet.

The Examiner, however, is now raising a new ground of rejection, again using *Goldfarb* but this time citing Figures 26A-27B, and Col. 21, line 13 to Col. 22, line 7 of the specification. These figures and recitations pertain to two embodiments of anchors 324 and 381. These anchors are described as merely providing attachment points for sutures, so that the sutures do not tear through the tissue. Figure 23B shows two anchors 324 attached to separate, adjacent leaflets, at their free edges. The sutures are then tied together. Figure 23B is the only figure that shows these anchors after installation with the sutures providing the support. The remaining figures are only illustrative of how the two halves of the anchors are joined together.

These *Goldfarb* anchors, thus, do not anticipate claim 1, which recites a support positioned away from free edges of said at least one valve leaflet, thereby allowing any free edges of the at least one valve leaflet to form a seal with free edges of adjacent leaflets during diastole. Even, *arguendo*, if the anchor were installed away from the free edges of the leaflet. The anchor, in and of itself, is not a support. It is merely an

attachment point for a suture. The combination of the anchor and the suture tied to another anchor and another suture constitute a support. This is only shown in Figure 23B as bridging across to another leaflet. Hence, the suture component of the support is not positioned away from the edge of the leaflet. Furthermore, after installation, the edges of the leaflet are no longer free.

For at least these reasons, Applicants submit that *Goldfarb* does not anticipate the presently claimed invention. As such, withdrawal of the present rejection and an indication of allowability of claim 1 are respectfully requested.

Further, dependent claims 2-6 depend from allowable claim 1 and are allowable for at least the same reasons. However, these claims further define and describe the present invention and are patentable over and above amended claim 1. Therefore, claims 2-6 are also allowable and thus withdrawal of the present rejection and an indication of allowability of claims 2-6 are also respectfully requested.

CONCLUSION

In view of the foregoing, it is demonstrated that *Goldfarb* does not currently anticipate pending claims 1-6. Thus, it is respectfully requested that the Examiner withdraw all of the rejections and issue a Notice of Allowance of all claims.

If for any reason direct communication with Applicant's attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,

Dated: August 28, 2009



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